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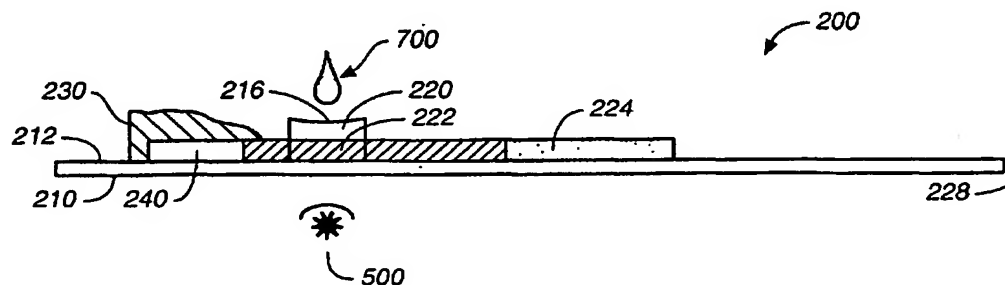
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ASSAY DEVICE, SYSTEM AND METHOD



(57) Abstract: A system for treating a blood sample having an analyte of interest comprises a strip having a membrane, respective portions which are provided for receiving the sample, for lysing cells of the sample to liberate hemoglobin, and for capturing glycated hemoglobin. The latter two portions of the membrane are treated with lysing and capture agents, respectively. A portion of the strip is provided for holding an eluting agent and for releasing the agent upon a release condition. A system for detecting analyte comprises an optical subsystem that is aligned with the strip to provide a signal corresponding to an amount of analyte, and an electronic subsystem for processing the signal to provide a result, such as an amount or percentage of glycated hemoglobin (Figure 5B). To use these systems, the user simply applies a small sample to the membrane and closes a door of the detection system over the strip such that the door triggers the release of the eluting agent. No sample pre-treatment is required. The preferably handheld system is a simple and convenient monitoring tool for the user, such as a diabetic patient who must monitor blood glucose on an on-going basis. While the systems are useful in the monitoring of blood glucose, they may be used for treating a sample other than blood and detecting an analyte other than an analyte in blood.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/35343

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12M 1/34; G01N 21/00, 33/00, 33/72, 33/543
US CL : 435/287.2, 287.7, 970; 436/66, 67, 86; 422/56, 57

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/287.2, 287.7, 970; 436/66, 67, 86; 422/56, 57

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched EAST/WEST

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MEDLINE, BIOSIS, SCISEARCH, EMBASE, CHEM ABSTRACTS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 6,677,158 B2 (HUD et al) 13 January 2004 (13.01.2004), see entire document.	1-79
Y,P	US 6,670,192 B1 (GALEN et al) 30 December 2003 (30.12.2003), see entire document.	1-79
A	US 5,541,117 A (KARL et al) 30 July 1996 (30.07.1996), see entire document.	1-79
A	US 5,837,546 A (ALLEN et al) 17 November 1998 (17.11.1998), see entire document.	1-79
A	US 5,242,842 A (SUNDREHAGEN) 07 September 1993 (07.09.1993), see entire document.	1-79
A	US 5,919,708 A (SUNDREHAGEN) 06 July 1999 (06.07.1999), see entire document.	1-79

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

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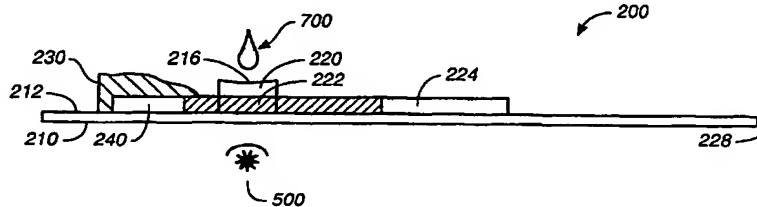
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(57) Abstract: A system for treating a blood sample having an analyte of interest comprises a strip having a membrane, respective portions which are provided for receiving the sample, for lysing cells of the sample to liberate hemoglobin, and for capturing glycated hemoglobin. The latter two portions of the membrane are treated with lysing and capture agents, respectively. A portion of the strip is provided for holding an eluting agent and for releasing the agent upon a release condition. A system for detecting analyte comprises an optical subsystem that is aligned with the strip to provide a signal corresponding to an amount of analyte, and an electronic subsystem for processing the signal to provide a result, such as an amount or percentage of glycated hemoglobin (Figure 5B). To use these systems, the user simply applies a small sample to the membrane and closes a door of the detection system over the strip such that the door triggers the release of the eluting agent. No sample pre-treatment is required. The preferably handheld system is a simple and convenient monitoring tool for the user, such as a diabetic patient who must monitor blood glucose on an on-going basis. While the systems are useful in the monitoring of blood glucose, they may be used for treating a sample other than blood and detecting an analyte other than an analyte in blood.

AMENDED CLAIMS

**[Received by the International Bureau on 16 September 2004 (16.09.04):
original claim 53 amended; remaining claims unchanged; (1 page)]**

providing a subsystem for detecting the at least one analyte, the detecting subsystem comprising:

- a second receiving portion for receiving the treating subsystem;
 - at least one source of light of at least one predetermined wavelength directed toward at least one of the first location and the second location when the treating subsystem is received in the second receiving portion; and
 - at least one light detector for receiving light reflected from at least one of the first location and the second location when the treating subsystem is received in the second receiving portion;
- receiving the treating subsystem in the second receiving portion of the detecting subsystem;
- applying the blood sample to the first receiving portion of the membrane;
 - allowing the eluting agent to flow downstream along the membrane;
 - directing light toward at least one of the first location and the second location;
- and
- receiving light reflected from at least one of the first location and the second location at least one light detector.

54. The method of claim 53, wherein the membrane has a property selected from a group consisting of wicking functionality, capillary functionality, porosity, and any combination thereof.

55. The method of claim 53, wherein the first reagent is selected from a group consisting of a detergent, a hypotonic solution, and any combination thereof.

56. The method of claim 53, wherein the eluting agent is selected from a group consisting of a buffer, a solvent, and any combination thereof.

57. The method of claim 53, wherein the second reagent is selected from a group consisting of an antibody, a chemical reagent comprising at least one ligand sufficient for binding the analyte, and any combination thereof.

58. The method of claim 53, wherein the analyte is glycated hemoglobin.

STATEMENT UNDER PCT ARTICLE 19(1)

Pursuant to PCT Article 19(1) and Rule 46, the enclosed replacement claim is hereby submitted to replace the originally filed claim. This letter is written in accordance with PCT Rule 46.5 and a marked copy of the claim, also enclosed, serves to point out the difference between the replaced sheet and the replacement sheet.

REMARKS

The claim has been amended merely to correct a minor inadvertent typographical or clerical oversight. A period is removed from the end of line 9 on page 37 of the originally filed claims. No new matter has been added to the claims by virtue of this amendment.

Entry of this Article 19 amendment is respectfully requested. Agent also respectfully requests that the application be re-published after entry of the subject amendment.

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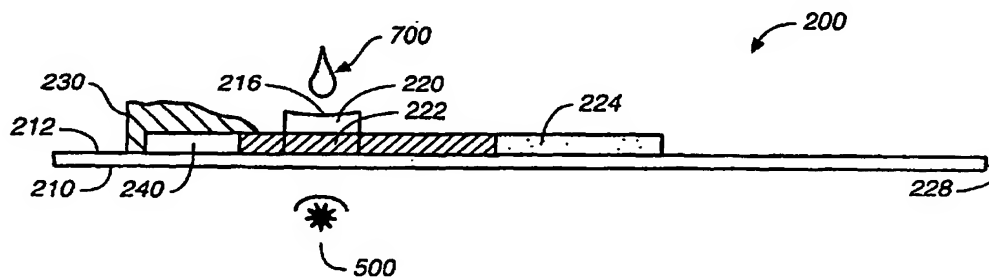
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[Continued on next page]

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